

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH  
and BIOGEN MA INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,  
et al.,

Defendants.

C.A. No. 17-823-LPS  
(Consolidated)

(C.A. No. 17-875-LPS)

**STIPULATION OF INFRINGEMENT BY SAWAI**

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen” or “Plaintiffs”) brought the following action against defendants Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. (“Sawai” or “Defendants”), alleging infringement of U.S. Patent Nos. 6,509,376 (“the ’376 patent”), 7,320,999 (“the ’999 patent”), 7,619,001 (“the ’001 patent”) 7,803,840 (“the ’840 patent), 8,759,393 (“the ’393 patent”), and 8,399,514 (“the ’514 patent”) by submission of Sawai’s Abbreviated New Drug Application (“ANDA”) No. 210285: *Biogen International GmbH, et al. v. Sawai USA, Inc.*, No. 1:17-cv-875-LPS, filed June 30, 2017 (“the 17-875 Action”). The Court later consolidated this action with *Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-823-LPS (the “Dimethyl Fumarate Consolidated Action”).

Biogen and Sawai stipulate in accordance with the terms and conditions as set forth herein.

IT IS HEREBY STIPULATED, subject to the approval of the Court:

1. For purposes of this Action only, Sawai stipulates that its submission of ANDA No. 210285 constitutes infringement of claims 1-4, 6, 8-13, 15, and 16 of the ’514 patent

pursuant to 35 U.S.C. § 271(e)(2)(A), provided those claims are not proven invalid or unenforceable.

2. By entering into this Stipulation, Sawai does not waive any invalidity defenses, including but not limited to its defenses that claims 1-4, 6, 8-13, 15, and 16 of the '514 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §101 et seq., including, e.g., § 103, and/or other judicially created bases for invalidation. This Stipulation shall not be used to argue that claims satisfy the definiteness requirements of 35 U.S.C. § 112, or for any other purpose other than the issue of infringement. This Stipulation may not be used or admitted in any proceeding other than the instant proceeding against Sawai concerning ANDA No. 210285.

3. The obligations imposed on Biogen and Sawai by this Stipulation shall be binding upon Biogen and Sawai and their respective parents, subsidiaries, affiliates and successors, including any successor-in-interest to Sawai's ANDA No. 210285.

4. This Stipulation grants no rights to Sawai under any patents or other proprietary rights.

ASHBY & GEDDES

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Dated: November 1, 2019

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 2019.

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Chief Judge